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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,760	01/05/2007	Marcello Allegretti	3765-0122PUS1	6665
2292 7590 01/14/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
HABTE, KAHISAY				
ART UNIT		PAPER NUMBER		
1624				
NOTIFICATION DATE		DELIVERY MODE		
01/14/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Office Action Summary****Application No.**

10/568,760

**Applicant(s)**

ALLEGRETTI ET AL.

**Examiner**

Kahsay T. Habte

**Art Unit**

1624

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

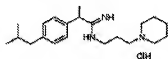
- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date 4/9/2008 and 2/21/2008
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1 and 12-19 are pending in this application.

### *Election/Restriction*

2. Applicant's election with traverse of Group IV (R = others) and a single disclosed species (compound 2a as shown below) filed on 01/05/2009 is acknowledged.



This corresponds to the R = H; Ar = 2-methylpropyl substituted phenyl and R' = N-propyl pyridyl, but the definition of R' in claim 1 is H, CH<sub>3</sub> and CH<sub>2</sub>CH<sub>3</sub>. It appears that the elected species does not exactly correspond to the definition of R' recited in claim 1 or claim 12. See first paragraph rejection below.

To expedite prosecution the examiner will proceed searching this case, even though the elected species does not correspond to the definition of the variables R and R' given in claims 1 and 12.

The traversal is on the ground(s) that "at least groups III and IV should be rejoined". Applicant's argument was persuasive. The examiner withdraws the restriction between Groups III and IV. This new restriction requirement replaces the previous one.

Group I, claim(s) 1, 12-17 (in part), drawn to 1,2,4-oxadiazine compounds where R'HN-C=N-R together form a 1,2,4-oxadiazine ring (see compound 5 at page 17).

Group II, claim(s) 1, 12-17 (in part), drawn to 1,3-imidazole compounds where R'HN-C=N-R together form a 1,3-imidazole ring (see compound 6 at page 17).

Group III, claim(s) 1, 12-17 (in part), drawn to others.

Group IV, claim(s) 18-19, drawn to a method of use.

### ***Advisory Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

**in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Note that the examiner search the elected species within Group IV (now Group III), but did not find any prior art. The search was expanded to cover the whole scope of Group III and the search was stopped when a prior art was found. After applicant's response to this Office Action, the examiner would make the action Final if he finds another prior art.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action.

Claims 18-19 would be rejoined once the conditions for rejoinder are met. It is recommended that applicants delete "prevention" from claim 18 and delete claim 19 or limit the inhibition to "*in vitro*".

**Information Disclosure Statement**

4. Applicant's Information Disclosure Statement, filed on 04/09/2008 and 02/21/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

**Claim Rejections - 35 USC § 102**

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

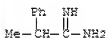
Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Delaby et al. Compt. rend, (1958), 346, 2905-6. See below the abstract.

L4 ANSWER 61 OF 62 CAPLUS COPYRIGHT 2009 ACS on STN  
ACCESSION NUMBER: 1958:113428 CAPLUS Full-text  
DOCUMENT NUMBER: 52:113428  
ORIGINAL REFERENCE NO.: 52:20024g-i,20025a  
TITLE: Research on hypocholesterol. Synthesis of amidines from substituted phenylacetic acids  
AUTHOR(S): Delaby, Raymond; Reynaud, Fierre; Lilly, Frank  
SOURCE: Compt. rend. (1958), 246, 2905-6  
DOCUMENT TYPE: Journal  
LANGUAGE: Unavailable  
AB PhCH<sub>2</sub>CN with Et<sub>2</sub>CO<sub>3</sub> in the presence of EtONa gives Et α-cyanophenylacetate, converted by treatment with alkyl halides (RX) and saponification with NaOH to PhCHRCN, e.g. 62% PhCHMeCN, b<sub>15</sub> 108°, 69% PhCHEtCN, b<sub>15</sub> 115° 72% PhCHPrCN, b<sub>14</sub> 130°, and 63%

PhCH(CSH17-n)CN, b0.1 133°. On passing dry HCl into solns. of the nitriles in EtOH, the iminoesters are formed, and addition of amines in the presence of AlCl3 gives N-substituted amidines. Thus, PhCHMeCN with HCl and EtOH gives PhCHMeC(:NH)OEt.HCl, m. 103.5°, and then PhCHMeC(:NH)NH2.HCl, m. 235°, is ethylated to PhCHMeC(:NH)NHEt, b0.2 109°, and PhCHMeC(:NH)NEt2, b0.1 111°, or phenylated to PhCHMeC(:NH)NHPh, m. 89°. Similarly, PhCHEtCN gives PhCHEtC(:NH)OEt.HCl, m. 98° then PhCHEtC(:NH)NH2.HCl, 232°, PhCHEtC(:NH)NHEt, b0.15 115°, or PhCHEtC(:NH)NEt2, m. 45°, and PhCHEtC(:NH)NHPh, m. 86°. Also, PhCHPrCN gives PhCHPrC(:NH)OEt.HCl, m. 82°, then PhCHPrC(:NH)NH2.HCl, m. 238°, PhCHPrC(:NH)NHEt, b3 152°, or PhCHPrC(:NH)NEt2, b0.1 102° and PhCHPrC(:NH)NHPh, m. 110.5°. PhCH(CSH17-n)CN gives the amidines PhCH(CSH17-n)C(:NH)NEt2, b0.3 160°, and PhCH(CSH17-n)-C(:NH)NHPh, m. 52°. The physiol. activity of the substituted amidines is being studied.

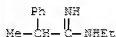
IT 78622-24-9F, Hydratropamidine, hydrochloride 91:29-53-7F  
 , Hydratropamidine, N-ethyl- 92579-12-9F, Hydratropamidine,  
 N-phenyl-  
 RL: FREF (Preparation)  
 (preparation of)

RN 78622-24-9 CAPLUS  
 CN Benzeneethanimidamide, α-methyl-, hydrochloride (1:1) (CA INDEX NAME)

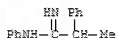


● HCl

RN 91429-53-7 CAPLUS  
CN Benzeneethanimidamide, N-ethyl- $\alpha$ -methyl- (CA INDEX NAME)



RN 92579-12-9 CAPLUS  
CN Benzeneethanimidamide,  $\alpha$ -methyl-N-phenyl- (CA INDEX NAME)



Cited reference teaches three compounds that are the same as applicants when applicant's formula (I) has the following definitions: R = H; R' = phenyl, ethyl or H; and Ar = phenyl.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

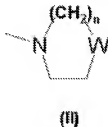
Claims 1, 12-13 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R = H, does not reasonably provide enablement for R = C1-C5-alkyl, phenyl etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to



use the invention commensurate in scope with these claims. Applicants define R as the following, but the specification is not enabled for such a scope.

- H, C<sub>1</sub>-C<sub>8</sub>-alkyl, phenyl, C<sub>1</sub>-C<sub>8</sub>-phenylalkyl, C<sub>1</sub>-C<sub>8</sub>-cycloalkyl, C<sub>1</sub>-C<sub>8</sub>-alkenyl, C<sub>1</sub>-C<sub>8</sub>-alkoxy;

- a residue of formula  $-(CH_2)_n-NR_aR_b$  wherein n is an integer from 0 to 5 and each R<sub>a</sub> and R<sub>b</sub>, which may be the same or different, are C<sub>1</sub>-C<sub>8</sub>-alkyl, C<sub>1</sub>-C<sub>8</sub>-alkenyl or, alternatively, R<sub>a</sub> and R<sub>b</sub>, together with the nitrogen atom to which they are bound, form a heterocycle from 3 to 7 members of formula (II),



In reviewing applicant's specification and chemical structure reported in Table 1 and applicants work from the CAS, none of the compounds have any substituents attached to =N except hydrogen.

It appears that applicants confused the definition of R with the definition of R'.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 1, the definition of R and R' appears to be confused. In the specification and in the search done by the examiner, it appear that the definition of R' to be that of R and the vice versa. Is the definition of R' = H, CH<sub>3</sub> and CH<sub>2</sub>CH<sub>3</sub>? It is recommended that applicants review this definition.

b. In claim 1 (page 3, lines 1-2), there are two extra periods in the middle of the claim. Where is the end of the claim? After line 1 at page 3 or after line 2 or after line 7?

c. In claim 16, the term "thiofene" is not clear. Do applicants mean "thiophene"?

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9:00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone

Art Unit: 1624

number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kahsay T. Habte/  
Primary Examiner, Art Unit 1624

KH  
January 12, 2009